BEFORE THE IOWA BOARD OF PHARMACY

Re:	)	
Pharmacy License of	)	Case No. 2012-52
BAUDER PHARMACY, INC.	)	
License No. 222	)	**STATEMENT OF CHARGES**
Respondent.	)	

COMES NOW, the Complainant, Lloyd K. Jessen, and states:

1. He is the Executive Director for the Iowa Board of Pharmacy (hereinafter, "Board") and files this Statement of Charges solely in his official capacity.

2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 155A and 272C (2011).

3. On December 12, 2011, the Board renewed Respondent's general pharmacy license number 222 for Bauder Pharmacy (hereinafter, "Respondent"), allowing Respondent to engage in the operation of a pharmacy subject to the laws of the State of Iowa and the rules of the Board.

4. At all times material to this statement of charges, Respondent was operating as a general pharmacy at 3802 Ingersoll Avenue, Des Moines, Iowa, with Mark E. Graziano as the pharmacist in charge.

A. CHARGES

COUNT I

Respondent is charged under Iowa Code §§ 124.308(3), 124.402(1), 155A.15(2)(c), 155A.15(2)(h) (2011) and 657 Iowa Administrative Code § 36.1(4)(ac) with failing to maintain adequate control over and accountability for controlled substances.

COUNT II

Respondent is charged under Iowa Code § 155A.15(2)(c), 155A.15(2)(i) and 657 Iowa Administrative Code § 10.15 with inadequate security and failure to establish effective controls against diversion of controlled substances.

COUNT III

Respondent is charged under Iowa Code §§ 124.306, 155A.15(2)(c), 155A.15(2)(h) and 657 Iowa Administrative Code § 10.34 with failure to keep and maintain records as required by the Controlled Substances Act.

COUNT IV

Respondent is charged under Iowa Code § 155A.15(2)(h) and 657 Iowa Administrative Code § 8.9 with failure to properly sign and date invoices for controlled substances.

COUNT V

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 10.21 with dispensing Schedule II controlled substances in quantities exceeding prescriber authorization.

COUNT VI

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 10.23 with failure to comply with requirements for the partial filling of Schedule II controlled substances.

COUNT VII

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 10.33 with failure to maintain complete and accurate perpetual inventories of Schedule II controlled substances.

COUNT VIII

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 10.35 with failure to maintain a complete and accurate inventory of controlled substances.

COUNT IX

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 21.5 with failure to document verification of controlled substance refills.

COUNT X

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 3.20 with failure to properly supervise dispensing functions that are delegated to non-pharmacists.

COUNT XI

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 6.13 with failure to maintain complete patient records.

COUNT XII

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code §§ 3.11 and 36.1(4)(aa) with failure to ensure that all pharmacy technicians have a current and active technician registration.

COUNT XIII

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 6.2 with failure to maintain required policies and procedures for the operation of a pharmacy.

COUNT XIV

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 6.7 with failure to provide proper security for prescription medications and pharmacy records stored in the basement.

COUNT XV

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 8.14 with failure to have required policies, procedures and documentation for pharmacy technician training.

COUNT XVI

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 8.26 with failure to have a continuous quality improvement program.

COUNT XVII

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code §§ 13.3, 13.6, 13.7, 13.11, 13.25, 13.27, 13.28, 13.29, and 13.31 with failure to meet minimum standards for sterile compounding.

COUNT XVIII

Respondent is charged under Iowa Code §§ 155A.15(2)(c) and 155A.15(2)(f) and 657 Iowa Administrative Code § 22.5 with failure to provide labeling and and record keeping for patient med paks.

COUNT XIX

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 36.1(4)(w) with failure to provide adequate patient counseling to patients.

B. CIRCUMSTANCES

An investigation was commenced on March 9, 2012, which revealed the following:

1. At all times material to this Statement of Charges, Respondent operated a general pharmacy at 3802 Ingersoll Avenue, Des Moines, Iowa 50312.

2. An audit of controlled substances handled by Bauder Pharmacy between January 1, 2008, and March 21, 2012, revealed a shortage of approximately 740,888 tablets of various strengths of hydrocodone APAP, a Schedule III controlled substance. This shortage was determined by obtaining information from the Automation of Reports and Consolidated Orders System (ARCOS) maintained by the U.S. Department of Justice, Drug Enforcement Administration. ARCOS is an automated, comprehensive drug reporting system which monitors the flow of certain DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level. Respondent acquired hydrocodone APAP products for Bauder Pharmacy from 14 different drug wholesalers between 2008 and 2012.

3. For the audit period of January 1, 2008 through March 21, 2012, ARCOS records indicate that Respondent ordered and received a total of 1,098,900 hydrocodone APAP tablets (all brands, all strengths). The majority of these hydrocodone APAP products were of one strength; hydrocodone APAP 7.5mg/500mg (593,700 tablets).

4. For the same audit period (January 1, 2008 through March 21, 2012), prescription monitoring program (PMP) records submitted by Respondent indicate that Respondent dispensed 358,012 hydrocodone APAP tablets (all brands, all strengths) to customers.

5. For the audit period January 1, 2008 through March 21, 2012, a total of 740,888 hydrocodone APAP tablets are not accounted for in Respondent's PMP dispensing records. Respondent has received, from wholesalers, 740,888 more tablets of hydrocodone APAP than Respondent has reported selling.

6. Shortages of hydrocodone APAP products at Bauder Pharmacy occurred as follows:
   Calendar Year 2008: 229,846 tablets;
   Calendar Year 2009: 163,185 tablets;
   Calendar Year 2010: 155,436 tablets;
   Calendar Year 2011: 182,732 tablets
   January-March, 2012: 9,689 tablets.

7. Two shopper surveys in which prescriptions were filled at Bauder Pharmacy on March 8, 2012, and March 14, 2012, revealed numerous deficiencies including inadequate patient counseling, lack of patient privacy, failing to obtain required patient information, mislabeling of a prescription vial, and dispensing prescription medication in non-childproof prescription containers.

8. An inspection of Bauder Pharmacy on March 16, 2012, revealed the following additional deficiencies:
   a) Technician Higgins' registration expired on September 30, 2010, and was not renewed in a timely manner.
   b) Bauder Pharmacy has no pertinent policies and procedures as required by Board rules.
   c) Security at Bauder Pharmacy for medications and records stored in the basement was found to be inadequate (second notice).
   d) Respondent, Mark Graziano, was not wearing a badge which identified him as a pharmacist (second notice).
   e) Bauder Pharmacy's controlled substance invoices were not signed and dated.
   f) Bauder Pharmacy has no policy or documentation of technician training.
   g) Bauder Pharmacy has no continuous quality improvement program
   h) Bauder Pharmacy dispensed a Schedule II prescription in a quantity larger than what was authorized.
   i) Bauder Pharmacy partially filled schedule II prescriptions past the 72 hour limitation.
   j) Bauder Pharmacy's Schedule II perpetual inventory does not accurately reflect dispensing, resulting in negative balances.
   k) Bauder Pharmacy's Schedule II invoices were not kept separate from Schedule III, IV and V invoices.
   l) Bauder Pharmacy's annual controlled substance inventory was missing the quantity for hydrocodone APAP 2.5/500mg
   m) Carisoprodol was not inventoried by Bauder Pharmacy when it became a Schedule IV controlled substance on January 11, 2012.
   n) Bauder Pharmacy had no policies and procedures for sterile compounding.
   o) Bauder Pharmacy had no quality assurance program for sterile compounding.
   p) Bauder Pharmacy had no training documentation for personnel involved with sterile compounding.
   q) Bauder Pharmacy had no batch records for sterile compounding and no labeling of product.
   r) Bauder Pharmacy gave a longer expiration date to low risk compounded products than allowed.
   s) Bauder Pharmacy has never conducted media fill testing.
   t) Bauder Pharmacy's sterile compounding room has areas that need repair.
   u) Bauder Pharmacy has no written cleaning procedures and no documentation of cleaning for sterile compounding areas.
   v) The sterile compounding areas at Bauder Pharmacy have only been certified once a year instead of twice a year (second notice); microbial sampling has never been conducted; there were no pressure differential monitors; and there were no procedures concerning environmental requirements.

w) Bauder Pharmacy had failed to document verification of controlled substance refills for the past two years.
x) Bauder Pharmacy had no labeling or record keeping for patient med paks.
y) Bauder Pharmacy has dispensed prescriptions in containers with non child-resistant packaging without proper authorization.
z) Bauder Pharmacy has reused prescription vials.

Wherefore, the Complainant prays that a hearing be held in this matter and that the Board take such action as it may deem to be appropriate under the law.

LLOYD K. JESSEN
Executive Director

On this 3rd day of May 2012, the Iowa Board of Pharmacy found probable cause to file this Statement of Charges and to order a hearing in this case.

SUSAN M. FREY, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Theresa Weeg
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa

PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served upon Respondent to the above cause by:

( ) personal service
( ) certified mail, return receipt requested
Article Number _____
( ) first class mail
( ) Facsimile
( ) other _____

on the _____ day of May 2012.

I declare that the statements above are true to the best of my information, knowledge and belief.

_____
Jean Rhodes, Compliance Officer

BEFORE THE IOWA BOARD OF PHARMACY

Re:	)	Case No. 2012-52
Controlled Substance Registration of	)	
BAUDER PHARMACY, INC.	)	**ORDER OF IMMEDIATE SUSPENSION**
Registration No. 1100280	)	**AND**
Respondent.	)	**ORDER TO SHOW CAUSE**
	)	

TO: BAUDER PHARMACY INC.
3802 Ingersoll Ave
Des Moines, Iowa 50312

NOTICE: Pursuant to the provisions of Iowa Code § 124.305(2) (2011) and 657 Iowa Administrative Code § 10.12(9), controlled substance registration number 1100280, issued to Bauder Pharmacy, Inc., is hereby **IMMEDIATELY SUSPENDED.**

NOTICE: Pursuant to the provisions of Iowa Code § 124.305(1) (2011) and 657 Iowa Administrative Code § 10.12(5), you are hereby ordered to appear before the Iowa Board of Pharmacy and show cause why controlled substance registration number 1100280, issued to Bauder Pharmacy, Inc., should not be revoked. **IF YOU DESIRE A HEARING REGARDING SUSPENSION AND POSSIBLE REVOCATION OF THIS CONTROLLED SUBSTANCE REGISTRATION, YOU MUST FILE A REQUEST FOR A HEARING BEFORE THE BOARD WITHIN THIRTY (30) DAYS OF ISSUANCE OF THIS ORDER.**

I. JURISDICTION

Pursuant to Iowa Code chapters 124 and 155A (2011), and 657 Iowa Administrative Code § 10.1, et seq., the Iowa Board of Pharmacy (hereinafter, "Board") has jurisdiction over those who manufacture, distribute, and dispense controlled substances in Iowa. On June 6, 2011, the Board issued to Bauder Pharmacy Inc. (hereinafter, "Respondent"), subject to the laws of the State of Iowa and the rules of the Board, a renewal of controlled substance registration number 1100280. At all times material to these proceedings, Respondent was operating a retail pharmacy at 3802 Ingersoll Avenue, Des Moines, Iowa 50312.

II. BASIS FOR ORDER TO SHOW CAUSE

On or about March 5, 2012, the Board commenced an investigation of Respondent which revealed the following:

1. Respondent operates a retail pharmacy located at 3802 Ingersoll Avenue, Des Moines, Iowa. On June 6, 2011, the Board issued Respondent a renewal of controlled substance registration number 1100280.
2. An audit of controlled substance dispensing records, performed in connection with the March 5, 2012 investigation, revealed that substantially greater quantities of controlled substances have been ordered by Respondent from wholesalers than were reported by Respondent as sold to pharmacy customers. Prescription monitoring program (PMP) records and the federal Drug Enforcement Administration's "automation of reports and consolidated orders system" (ARCOS) records were reviewed. Comparison and analysis of the records revealed that Respondent has followed a practice of ordering from an unusually diverse number of drug wholesalers. From 2008-2012, fourteen wholesalers provided hydrocodone APAP to Respondent in three strengths: 10/325, 5/500 and 7.5/500. Hydrocodone APAP is a Schedule III controlled substance.
3. For the audit period of January 1, 2008 through March 21, 2012, ARCOS records indicate that Respondent ordered and received a total of 1,098,900 hydrocodone APAP tablets (all brands, all strengths). The majority of these hydrocodone products were of one strength; hydrocodone APAP 7.5/500 (593,700 tablets).
4. For the same audit period (January 1, 2008 through March 21, 2012), PMP records submitted by Respondent indicate that Respondent dispensed 358,012 Hydrocodone APAP tablets (all brands, all strengths) to customers.

5. For the audit period January 1, 2008 through March 21, 2012, a total of 740,888 hydrocodone APAP tablets are not accounted for in Respondent's PMP dispensing records. Respondent has received, from wholesalers, 740,888 more tablets of hydrocodone APAP than Respondent has reported selling.

6. Analyzed on an annual basis, Respondent's unaccounted for hydrocodone APAP tablets number as follows:

   2008 – 229,846 tablets
   2009 – 163,185 tablets
   2010 – 155,436 tablets
   2011 – 182,732 tablets
   2012 – 9,689 tablets

7. An audit of Respondent's PMP-reported Oxycodone sales – again utilizing a comparison of ARCOS records of controlled substance purchases with PMP records of controlled substance sales – revealed more Oxycodone product dispensing than would be possible with the supplies delivered by wholesalers. For the audit period January 1, 2008 through March 21, 2012, Respondent received 1,293 fewer Oxycodone tablets than Respondent reported selling. Additionally, Respondent's submissions to the PMP indicate Respondent was charging for brand name Oxycodone products (Endocet, Roxicet and Percocet) while dispensing generic Oxycodone products. During the audit period, Respondent's reports to the PMP indicate 5,269 tablets of Roxicet were reported dispensed. However, during the same period, only 1,500 tablets of Roxicet were shipped to Respondent by wholesalers.

III. BASIS FOR ORDER OF IMMEDIATE SUSPENSION

The Board finds as follows:

1. For the audit period January 1, 2008 through March 21, 2012, a total of 740,888 hydrocodone APAP tablets, shipped to Respondent by wholesalers, are not accounted for by Respondent's PMP records of prescription sales.
2. The void in Respondent's dispensing (PMP) records indicates that, for the audit period January 1, 2008 through March 21, 2012, approximately 740,888 hydrocodone APAP tablets were diverted or dispensed in violation of the provisions of Iowa Code chapters 124 and 155A (2011).
3. Hydrocodone APAP is an addictive Schedule III controlled substance, frequently distributed illegally. The Iowa legislature has determined that use of hydrocodone APAP may lead to moderate physical dependence and high psychological dependence. Iowa Code § 124.207 (2011).
4. Illegal distribution of large quantities of hydrocodone APAP represents a threat to the public health and safety due to the addictive nature of the drug. The assembled evidence indicates that Respondent has engaged in a steady, repeated practice of illegal hydrocodone APAP distribution over a period of more than four years. The amount of hydrocodone APAP not accounted for in Respondent's pharmacy records – 740,888 hydrocodone APAP tablets – is very large considering the moderate size of Respondent pharmacy and the emphasis the Board places on accurate record keeping and security of controlled substances. Approximately two thirds of the hydrocodone APAP being purchased by Respondent is not accounted for in the PMP records provided by Respondent. There is no likelihood that the substantial discrepancy between wholesaler shipping records and Respondent's dispensing records can be explained as a simple record-keeping error.

5. Records indicate that another controlled substance, Oxycodone – in generic form, is being sold to patients as name-brand products such as Endocet, Roxicet and Percocet.

IV. ORDER

1. Respondent's Controlled Substance Registration is IMMEDIATELY SUSPENDED UPON SERVICE.
2. Respondent is hereby ORDERED to immediately upon service return controlled substance certificate of registration, number 1100280, to the Board.
3. Respondent is hereby ORDERED to immediately deliver all controlled substances in the Respondent's possession to the Board or authorized agent of the Board.
4. Respondent is ORDERED to appear before the Iowa Board of Pharmacy and show cause why controlled substance registration number 1100280, issued in Respondent's name, should not be revoked. If Respondent wishes to have a hearing before the Board in response to this Order, Respondent must notify the Board within thirty (30) days of the date of this Order. Respondent's request for a hearing should be directed to Lloyd Jessen, Executive Director, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. The Board office telephone number is (515) 281-5944. A hearing is tentatively set for 9:00 a.m., June 26, 2012, at the Board's offices, pending Respondent's request for a hearing.

IF RESPONDENT DOES NOT REQUEST HEARING IN THIS MATTER WITHIN THIRTY DAYS OF THE DATE OF THIS ORDER, RESPONDENT'S CONTROLLED SUBSTANCE REGISTRATION WILL BE DEEMED REVOKED WITHOUT FURTHER ORDER OF THE BOARD.

IT IS SO ORDERED THIS 3rd day of May 2012.

Susan M. Frey

SUSAN M. FREY, Chairperson
Iowa Board of Pharmacy

cc: Theresa Weeg, Assistant Iowa Attorney General
Drug Enforcement Administration, Des Moines

PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served upon Respondent to the above cause by:

( ) personal service
( ) certified mail, return receipt requested
Article Number _____
( ) first class mail
( ) facsimile
( ) other _____

on the _____ day of May 2012.

I declare that the statements above are true to the best of my information, knowledge and belief.

_____
Jean Rhodes, Compliance Officer